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A national patient and public colorectal research agenda: integration of consumer perspectives in bowel disease through early consultation

A. G. K. McNair^{*†} , N. Heywood[‡], J. Tiernan[§], A. Verjee^{¶**}, S. P. Bach^{††‡‡},
N. S. Fearnhead^{§§¶¶}, On behalf of ORACLE Collaboration^a

^{*}Centre for Surgical Research, School of Social and Community Medicine, University of Bristol, Bristol, UK, [†]National Cancer Research Institute, London, UK, [‡]University Hospital of South Manchester, Wythenshaw, UK, [§]John Goligher Colorectal Unit, St James's University Hospital, Leeds, UK, [¶]Bowel Disease Research Foundation, London, UK, ^{**}Crohn's and Colitis UK, St Albans, UK, ^{††}Colorectal Surgery, University of Birmingham, Birmingham, UK, ^{‡‡}Royal College of Surgeons of England, Lincoln's Inn Fields, London, UK, ^{§§}Addenbrooke's Hospital, Cambridge, UK and ^{¶¶}Research and Audit Committee, Association of Coloproctology of Great Britain and Ireland, London, UK

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Abstract

Aim There is a recognized need to include the views of patients and the public in prioritizing health research. This study aimed: (i) to explore patients' views on colorectal research; and (ii) to prioritize research topics with patients and the public.

Method In phase 1, 12 charitable organizations and patient groups with an interest in bowel disease were invited to attend a consultation exercise. Participants were briefed on 25 colorectal research topics prioritized by members of the Association of Coloproctology of Great Britain and Ireland. Focus groups were conducted and discussions were recorded with field notes. Analysis was conducted using principles of thematic analysis. In phase 2, a free public consultation was undertaken. Participants were recruited from newspaper advertisements, were briefed on the same research topics and were asked to rate the importance of each on a five-point Likert scale. Descriptive statistics were used to rank the topics. Univariable linear regression compared recorded demographic details with mean topic scores.

Results Focus groups were attended by 12 patients who highlighted the importance of patient-centred

information for trial recruitment and when selecting outcome measures. Some 360 people attended the public consultation, of whom 277 (77%) were recruited. Participants rated 'What is the best way to treat early cancer in the back passage?' highest, with 227 (85%) scoring it 4 or 5. There was no correlation between participant demographics and mean topic scores.

Conclusion The present study prioritized a colorectal research agenda with the input of patients and the public. Further research is required to translate this agenda into real improvements in patient care.

Keywords Patient and public involvement, research methodology, research priorities, bowel disease, outcome selection, priority setting partnership

What does this paper add to the literature?

Patient and public involvement in research is critical to ensure appropriate resource allocation, but there are no evidence-based guidelines for research in colorectal surgery. The study explored patients' views on key colorectal research topics and prioritized their importance. It is recommended that this agenda is used to plan future patient-centred research.

Introduction

Surgical research is burdened by specific difficulties that have led to a paucity of high-quality studies and trials

[1–3]. Traditionally, academics have defined research topics and designed studies without the involvement of those who have direct experience of disease and its treatment. Recent publications have called for the involvement of patients and their representatives in research at a much earlier stage, ideally helping to define research topics that they perceive to be of value [4–6]. This has been helped by funding bodies, patient

Correspondence to: Nicola S. Fearnhead, Cambridge Colorectal Unit, Addenbrookes Hospital, Cambridge, CB2 0QQ UK.
E-mail: nicola.fearnhead@addenbrookes.nhs.uk

^aORACLE Collaboration are listed in Appendix 1.

groups, editors and health policy makers who place an emphasis on patient and public consultation when designing clinical research [2–4,7–9].

Since 2004, the James Lind Alliance (JLA) has developed a Priority Setting Partnership (PSP) to enable patients, carers and clinicians to work together to identify and prioritize uncertainties about treatment. Their recent round table report, a collaboration between the National Institute for Clinical Excellence (NICE), the JLA, Association of Medical Research Charities (AMRC) and member charities, highlighted ‘a need to increase the perceived power of patient views’ and demonstrated strong support for programmes including research questions based on prioritized patient, carer and clinician input [10].

There is a demonstrable mismatch between the views of clinicians and patients in identifying topics for research [7]. This is particularly relevant in colorectal surgery, in which the potential benefits are balanced against the potential of the long-term deleterious impact on quality of life. The balance between the benefits and risks of colorectal surgery is perhaps best illustrated in perianal Crohn’s disease [11] but is also well-recognized in cancer treatment [12,13]. Appropriately, therefore, much research has been carried out to explore patients’ treatment preferences in colorectal surgery [14]. There is, however, little evidence demonstrating which colorectal surgical topic should be the focus of research.

The Association of Coloproctology of Great Britain and Ireland (ACPGBI) has recently conducted a modified Delphi exercise to define research priorities in bowel disease, with the financial and administrative support of its research charity, the Bowel Disease Research Foundation (BDRF) [15]. Delphi methodology is an established technique for reaching a consensus opinion among a group of experts and is used commonly in the health and social sciences [16–19]. The entire ACPGBI membership of practising colorectal surgeons was surveyed and this generated over 500 potential research questions. Through a series of iterative voting rounds, a list of 25 prioritized research questions was identified: 15 relating to colorectal cancer and 10 relating to diverse topics, including benign disease, surgical technique and clinical governance.

In the current study the questions were posed to patients to gather a collective patient and public perspective on the prioritized areas of research, to focus on patient-centred outcomes, views and values. The views were obtained before developing research strategies based on the questions, and, most importantly, to allow patients to define their own order of priority. The overall aims were: (i) to explore patients’ views on the

research topics; and (ii) to prioritize research topics with the input of patients and the public. It is anticipated that this novel approach will enable genuine and integrated patient collaboration in defining and developing future research for questions relating to bowel disease.

Method

The scope of this consultation exercise included patients, carers, family and members of the public with an interest in bowel disease, including cancer, inflammatory bowel disease or other benign conditions. Paediatric colorectal disease was excluded. The study is presented in two phases as follows: (i) exploration of patients’ views on the research topics; and (ii) prioritization of the research topics.

Phase I: Exploration of patients’ views on the research topic

Charitable organizations and patient groups with an interest in bowel disease were invited to attend a 1-day consultation exercise in March 2015, hosted by the Royal College of Surgeons of England in London, UK. The organizations present included the BDRF, the ACPGBI, the Colostomy Association, the British Society of Gastroenterology, IA, the Ileostomy and Internal Pouch Support Group, Crohn’s and Colitis United Kingdom (CCUK), the Kingston Trust, Beating Bowel Cancer, Bowel Cancer United Kingdom, the Core Charity, the National Institute for Health Research Consumer Liaison Group and the Royal College of Surgeons of England Patient Liaison Group. Consultant surgeons and surgical trainees with an interest in research prioritization were invited to participate through personal correspondence. The chairwoman (AV) was a patient and Trustee of the BDRF and CCUK and is experienced in patient consultation exercises.

Personal introductions were made by all participants at the outset of the meeting to gain an understanding of their background and role in the exercise. The 25 research questions identified from the ACPGBI professional Delphi exercise research agenda were then summarized in lay language. Participants were divided into focus groups consisting of patients, surgical trainees and practising consultant surgeons to explore patients’ views on each research topic. Focus groups varied in size from six to 10 participants, and each session, discussing an individual topic, lasted for approximately 30 min. All groups were supported by consultant surgeons with an in-depth understanding of colorectal disease. Discussions were centred on the one open-ended question of

‘What do you feel is important about [the topic] from a patient’s perspective?’. Patients were free to discuss any views they considered relevant. Clinicians explained medical terminology or research methodology, and provided a clinical perspective when this was sought by patients. Following each session, participants fed back their views on each topic to the wider group. Disparate opinions were actively sought and discussed.

Data collection and analysis

Data were collected in the form of anonymized field notes created by eight participating observers in the focus groups. These included consultant or trainee surgeons with an in-depth understanding of colorectal disease. Researchers were the participating observers and recorded patients’ views on the research topics and their rationale on notepads. Direct quotations were recorded to illustrate patients’ views where appropriate. The participating observers were provided with guidance by the senior study team but received no formal training. Analysis was conducted using the principles of qualitative thematic analysis [20]. Field notes were read and re-read through a process of data familiarization. Sections of text were coded independently by two researchers (NF and AM) and a preliminary set of themes was developed. A process of constant comparison between field notes was used to refine the themes and deviant cases were sought to challenge emerging theories. The themes were discussed with the wider research team and further refined. Data are presented as three main themes, with quotation of the source documents provided as illustration.

Phase 2: Patient and public prioritization

Patient prioritization was conducted during the consultation exercise (described above). Blinding to clinician prioritization was ensured by random allocation of questions to letters of the Greek alphabet. Public prioritization was conducted at a free event at the Digestive Disorders Federation conference held in June 2015, London, UK. Participants were recruited through advertising in the London Evening Standard newspaper and through marketing material created by the BDRF and the Core Charity. Included were any individuals who wanted to prioritize bowel disease research (such as patients, carers, family members and healthy individuals) and there were no exclusions.

Patients and the public participants were presented with a summary of each research question in lay language, and were then asked to rate its importance on a five-point Likert scale with scores ranging from 1

(lowest priority) to 5 (highest priority). One question was added to the voting at the request of the funder (CORE): ‘How can diet, probiotics and medicines help in irritable bowel syndrome?’. Clinical and sociodemographic details were recorded in the public consultation and included sex, age, country of residence, self-reported healthcare problems, past surgical history and presence of stoma. Self-reported healthcare problems were defined as ‘cancer’, ‘inflammatory bowel disease’, ‘other bowel disease’, ‘other nonbowel disease’ or ‘none’. Past surgical history was defined as ‘bowel surgery’, ‘bottom surgery’, ‘other surgery’ or ‘none’.

Analysis

Research topics were categorized as ‘high priority’ if they were rated as 4 or 5 on the Likert scale and as ‘low priority’ if they were rated as 1 or 2. Descriptive statistics were used to rank the importance of the research topics. Public consultation data are presented overall, and with subgroup analysis of those participants who identified themselves as patients. Univariable linear regression was used to explore the association between mean question scores and clinical and sociodemographic variables in the public consultation. There were no *a priori* assumptions that were planned to be analysed in a multivariable model.

Results

Phase 1: Exploration of patients’ views on the research topic

There were 25 participants in the initial patient consultation exercise: 11 patients, each with personal experience of bowel disease; one administrator from the host charity; nine colorectal consultants; and four general surgical trainees. Geographical representation included England, Wales and Scotland. The major themes identified through discussion of the 25 questions were: (i) that patients were supportive of research questions; (ii) the importance of good communication; and (iii) the importance of selecting patient-centred outcomes in research. These themes are discussed in more detail below.

Patients were supportive of the research questions

Patients expressed support for all the research questions, a view that was explained by an altruistic attitude towards future sufferers of bowel disease. Of paramount importance was patient-centred research, in which disease sufferers are involved in the design of research

questions, including consideration of the intervention involved in the trial and identification of the outcome measures.

Patients' support was extended to the inclusion of anonymized patient information on national databases. There was unanimous recognition of the essential role that such databases play in designing research studies but also in potentially highlighting dangerous or ineffective treatments. High-quality large-scale information with appropriate, but not inhibitory, data protection and sharing was felt to be in the common interest for patients and researchers alike. National tissue banks and extra biopsy samples were considered acceptable to aid scientific progression if they could provide more accurate ways of treating cancer and allow tailor-made personalized treatments.

Concern about some of the research questions was raised, however. Avoiding delays in treatment after initial diagnosis was a high priority for patients as 'once I knew I had cancer, I wanted to start treatment tomorrow' (discussion of question Alpha). The need for prompt treatment was highlighted in the context of tumour progression 'it might sound weird, but I had an idea that if I sat in a quiet room, I could hear the tumour growing' (discussion of question Eta). Acceptance of delay to allow enrolment in trials would need to be clearly explained with good communication about research studies, re-affirming that delay would not have a negative impact on successful outcome but may actually carry potential benefit, especially if neoadjuvant intervention is the proposed research intervention.

The importance of good communication

Patients' desire for high-quality information during study recruitment was reflected in discussions about every research question. Patients were of the opinion that 'it's the information you are given' (discussion of question Delta) and 'the way you, the clinician, put the questions across' that best informs the decision to take part in research. 'Communication is key' (discussion of question Phi) when presenting different treatment options in the recruitment phase, taking time to discuss complications and manage patient expectations.

Most patients felt overwhelmed by the amount of information given when told of the diagnosis, for example, 'the first day I found out about cancer was not the right day to talk about my treatment options' (discussion of question Iota). Giving information for recruitment into research requires careful explanation and allowing patients 'time to digest information'.

Trust in the clinician was felt to be a major influence for recruitment to trials. One patient said, 'Do not underestimate the trust and respect a patient has in their clinician, you are in the hands of the professionals' (discussion of question Delta). Although 'people trust their doctors to give them good advice' patients would like their views to be taken into account.

Particular emphasis was placed on the communication of information about stomas. This was not in response to any specific research question, but was highlighted across the focus groups. Patients were critical of a stoma being presented as a treatment failure: 'A stoma is not a negative thing. Patients don't want a small stoma – they want one that works, not an attractive one. If a surgeon feels for even one moment that a stoma is a bad thing, then that is what stays in your head' (Discussion of question Xi). Patients felt that it is unacceptable for the medical profession to present a stoma as a last resort, and that there must be a more positive message, 'I'll give you a stoma, and your quality of life will be much improved'. Patients felt that it was more important to communicate that 'having a stoma does not stop you from having a full and active life' (discussion of question Xi), and importantly that it may be the best available therapeutic option to regain health. Likewise, implication that a stoma was temporary, when it was likely to be permanent, was felt to be negative as patients tended to put life on hold, pending a reversal that would probably never happen for good medical reasons. Patients also expressed the need for better information about how to avoid stoma complications, particularly parastomal hernia, and to be given sufficient advice and support on discharge.

The importance of patient-centred outcome selection

The selection of patient-centred end-points was considered important by the focus groups. For example, concern was raised about evaluating fistulating perianal Crohn's disease by measuring rates of healing or recurrence. Participants instead described the need to evaluate the impact of treatment on quality of life such as 'a measure of lost nights of sleep' (discussion of question Eta). In other benign conditions, it was noted that 'Improved function is more important than recurrence as it improves quality of life' (discussion of question Upsilon). Where there was a lack of patient-centred outcomes available, participants voiced the need for their involvement in developing them in the future.

In cancer-related questions, patients considered long-term survival to be critical, with views such as ‘Only do a smaller surgery if you are able to remove the cancer properly’ (discussion of question Eta). Surgeons should ‘be specific in how damage is measured’ (discussion of question Eta) because anxiety generated from fear of recurrence and spread can be

a strong motivator for overtreatment. Patients reported anxiety about the effects of surgery and radiotherapy on bladder, bowel and sexual function, and of the toxicity of chemotherapy and radiotherapy, but wanted specific information on how this would affect them as an individual rather than that given in overall statistics. Survival was not the only important

Table 1 Prioritization of cancer questions in patient consultation: proportion of participants rating each question as ‘low’ (1 or 2 on the Likert scale) or ‘high’ (4 or 5 on the Likert scale) in importance ($n = 12$).

| Question | Category | Low importance | | High importance | |
|--|-----------|----------------|----|-----------------|-----|
| | | <i>n</i> | % | <i>n</i> | % |
| What is the impact of treatment for bowel and anal cancers on quality of life? | Cancer | 0 | | 12 | 100 |
| How do we improve screening for bowel cancer? | Cancer | 0 | | 12 | 100 |
| How do we personalize treatment for cancer of the back passage using genetics? | Cancer | 0 | | 11 | 92 |
| Why do some patients develop spread from bowel cancer? | Cancer | 0 | | 10 | 83 |
| Which polyps predict risk of developing bowel cancer? | Cancer | 1 | 9 | 9 | 75 |
| What is the best way to check that cancers of the back passage do not come back? | Cancer | 1 | 10 | 8 | 67 |
| What is the best way to look after patients with Crohn’s disease with fistulas around their bottoms? | Noncancer | 0 | | 8 | 67 |
| What are the best ways to prevent and fix hernias beside stomas? | Noncancer | 2 | 18 | 8 | 67 |
| Does reporting surgeon outcomes improve care? | Noncancer | 2 | 18 | 8 | 67 |
| How can we improve care for patients with severe infection related to their bowels? | Noncancer | 0 | | 8 | 67 |
| What is the best way to treat early cancers in the back passage? | Cancer | 0 | | 6 | 50 |
| When should a join in the bowel have a temporary stoma made above the join? | Noncancer | 2 | 18 | 6 | 50 |
| How do we best treat polyp cancers removed at colonoscopy? | Cancer | 1 | 9 | 6 | 50 |
| When should we operate to remove bowel cancer that has spread to the liver or lungs? | Cancer | 1 | 9 | 6 | 50 |
| Is chemotherapy better before or after surgery for more advanced bowel cancers? | Cancer | 3 | 27 | 5 | 42 |
| When is it best to use surgery to remove Crohn’s disease affecting the bowel? | Noncancer | 0 | | 5 | 42 |
| Is there benefit from preoperative radiotherapy in back passage cancers which could be removed with surgery? | Cancer | 1 | 9 | 5 | 42 |
| What is the best way to close the ‘hole’ when the anus is removed? | Noncancer | 1 | 9 | 5 | 42 |
| What is the best way to look after patients with infection from diverticulitis? | Noncancer | 2 | 18 | 5 | 42 |
| How can we reduce the chances of leakage from a join in the bowel? | Noncancer | 3 | 27 | 4 | 36 |
| Can problems with defaecation be improved by surgery? | Noncancer | 2 | 18 | 4 | 36 |
| Is a more radical approach to surgery for advanced cancers in the back passage beneficial? | Cancer | 2 | 18 | 3 | 27 |
| How do we stop the bowel going on ‘strike’ after surgery? | Noncancer | 2 | 18 | 3 | 27 |
| How should we treat patients with cancer in the back passage if they have a really good response to chemoradiotherapy? | Cancer | 4 | 36 | 2 | 18 |

Table 2 Demographics of participants in public and lay consultations.

| Variable | All participants | Patients |
|--------------|------------------|----------|
| Total | 277 | 80 |
| Sex | | |
| Female | 146 (53) | 41 (51) |
| Male | 99 (36) | 31 (39) |
| Not declared | 32 (11) | 8 (10) |
| Age (years) | | |
| < 40 | 51 (18) | 8 (10) |
| 41–60 | 105 (38) | 36 (45) |
| 61–80 | 107 (39) | 30 (38) |
| > 80 | 5 (2) | 3 (4) |
| Not declared | 9 (3) | 3 (4) |
| Location | | |
| England | 262 (95) | 79 (99) |
| Wales | 2 (1) | 1 (1) |
| Outside UK | 2 (1) | 0 |
| Not declared | 11 (4) | 0 |
| Surgery | | |
| Yes | 48 (17) | 27 (34) |
| No | 209 (75) | 48 (60) |
| Not declared | 20 (8) | 5 (6) |
| Stoma | | |
| Yes | 2 (1) | 1 (1) |
| No | 256 (92) | 74 (93) |
| Not declared | 19 (7) | 5 (6) |

Values are given as *n* (%).

Table 3 Univariable linear regression of total mean score according to participant characteristics.

| Characteristic | <i>n</i> | Difference in mean score | 95% CI | <i>P</i> |
|----------------|----------|--------------------------|-------------|----------|
| Participant | | | | |
| Nonpatient* | 176 | 0 | | |
| Patient | 77 | 0.1 | −0.1 to 0.3 | 0.25 |
| Sex | | | | |
| Female* | 145 | 0 | | |
| Male | 98 | −0.1 | −0.2 to 0.1 | 0.24 |
| Age (years) | | | | |
| 21–40* | 51 | 0 | | |
| 41–60 | 105 | 0.2 | −0.0 to 0.4 | |
| 61–80 | 107 | 0.3 | 0.1 to 0.5 | |
| < 80 | 5 | 0.2 | −0.4 to 0.7 | 0.06 |
| Surgery | | | | |
| No* | 27 | 0 | | |
| Yes | 48 | −0.1 | −0.4 to 0.2 | 0.43 |

*Baseline category for comparison.

outcome to patients and researchers were urged to ‘also look at functional outcomes, not just survival and recurrence’.

Phase 2: Patient and public prioritization

Patient prioritization

The results of the patient prioritization exercise are presented in Table 1. Overall, the cancer questions received the highest priority, with questions about quality of life after bowel cancer treatment and screening receiving maximum scores. Other key cancer priorities were perceived as personalization of treatment through knowledge of genetic prediction and prevention of metastatic disease. This order of priority contrasted markedly with the prioritization favoured by the surgeon by whom questions about organ preservation in rectal cancer treatment were ranked highest.

Although noncancer questions did not achieve scores at the same level as cancer questions, there was a significant cluster of high-scoring questions related to the outcome after anastomotic leakage, intra-abdominal sepsis and fistulating perianal Crohn's disease. There was a wide spread of scoring of the questions in this exercise, which may be a reflection of the preceding in-depth consultations held.

Public consultation

The public consultation exercise was attended by 360 patients, carers and lay representatives, of whom 277 (77%) completed demographic registration forms and were included in the final analysis. Participant demographics are reported in Table 2. A minority (*n* = 77; 25%) identified themselves as patients; half (*n* = 146; 49%) were women and most (*n* = 212; 71%) were between 40 and 80 years of age. Univariable linear regression did not identify any correlation between demographic variables and mean question rating scores, and a multivariable model was therefore not constructed (Table 3).

Results of the public prioritization exercise are presented in Table 4. There were some missing responses. Most complete was the question ‘How can we improve care for patients with severe infection related to their bowels?’ (271/277; 98%) and least complete was ‘How can diet, probiotics and medicine help in irritable bowel syndrome?’ (257/277; 93%). Ratings of cancer and non-cancer questions were much more heterogeneous in this exercise, but were still rated highly. The highest rated question was ‘What is the best way to treat early cancers in the back passage?’ [227 (85% of respondents) gave a rating of high importance and five (2%) gave a rating of low importance] followed by ‘How can we reduce the chances of leakage from a join in the bowel?’ [222 (83% of respondents) gave a rating of high importance and 13 (5%) gave a rating of low importance]. The lowest rated question was ‘Does reporting surgeon outcomes improve

Table 4 Prioritization of cancer questions by all participants attending the public consultation: proportion of participants rating each question as 'low' (1 or 2 on the Likert scale) or 'high' (4 or 5 on the Likert scale) in importance.

| Question | Category | Total no. of participants | Low importance | | High importance | |
|--|-----------|---------------------------|----------------|----|-----------------|----|
| | | | <i>n</i> | % | <i>n</i> | % |
| What is the best way to treat early cancers in the back passage? | Cancer | 268 | 5 | 2 | 227 | 85 |
| How can we reduce the chances of leakage from a join in the bowel? | Noncancer | 268 | 13 | 5 | 222 | 83 |
| Which polyps predict risk of developing bowel cancer? | Cancer | 269 | 15 | 6 | 220 | 82 |
| How can diet, probiotics and medicines help in irritable bowel syndrome? | Noncancer | 257 | 15 | 6 | 210 | 82 |
| How can we improve care for patients with severe infection related to their bowels? | Noncancer | 271 | 18 | 7 | 214 | 79 |
| What is the best way to check that cancers of the back passage do not come back? | Cancer | 266 | 17 | 6 | 206 | 77 |
| What is the best way to look after patients with Crohn's disease with fistulas around their bottoms? | Noncancer | 266 | 15 | 6 | 205 | 77 |
| How do we personalize treatment for cancer of the back passage using genetics? | Cancer | 264 | 22 | 8 | 201 | 76 |
| How do we improve screening for bowel cancer? | Cancer | 269 | 31 | 12 | 204 | 76 |
| Why do some patients develop spread from bowel cancer? | Cancer | 265 | 21 | 8 | 196 | 74 |
| What is the best way to close the 'hole' when the anus is removed? | Noncancer | 267 | 27 | 10 | 187 | 70 |
| How do we best treat polyp cancers removed at colonoscopy? | Cancer | 270 | 18 | 7 | 187 | 69 |
| What is the impact of treatment for bowel and anal cancers on quality of life? | Cancer | 267 | 22 | 8 | 184 | 69 |
| What is the best way to look after patients with infection from diverticulitis? | Noncancer | 270 | 28 | 10 | 177 | 66 |
| Is chemotherapy better before or after surgery for more advanced bowel cancers? | Cancer | 266 | 40 | 15 | 160 | 60 |
| How should we treat patients with cancer in the back passage if they have a really good response to chemoradiotherapy? | Cancer | 264 | 44 | 17 | 156 | 59 |
| Is a more radical approach to surgery for advanced cancers in the back passage beneficial? | Cancer | 267 | 40 | 15 | 151 | 57 |
| If bowel cancer has spread but responds to chemotherapy, is it worth operating on the primary bowel tumour? | Cancer | 261 | 32 | 12 | 145 | 56 |
| When should we operate to remove bowel cancer that has spread to the liver or lungs? | Cancer | 264 | 48 | 18 | 148 | 56 |
| When is it best to use surgery to remove Crohn's disease affecting the bowel? | Noncancer | 263 | 43 | 16 | 148 | 56 |
| When should a join in the bowel have a temporary stoma made above the join? | Noncancer | 263 | 38 | 14 | 145 | 55 |
| What are the best ways to prevent and fix hernias beside stomas? | Noncancer | 266 | 53 | 20 | 139 | 52 |

Table 4 (Continued).

| Question | Category | Total no. of participants | Low importance | | High importance | |
|--|-----------|---------------------------|----------------|----|-----------------|----|
| | | | <i>n</i> | % | <i>n</i> | % |
| Can problems with defaecation be improved by surgery? | Noncancer | 264 | 64 | 24 | 134 | 51 |
| Is there benefit from preoperative radiotherapy in back passage cancers which could be removed with surgery? | Cancer | 264 | 43 | 16 | 130 | 49 |
| How do we stop the bowel going on 'strike' after surgery? | Noncancer | 264 | 59 | 22 | 130 | 49 |
| Does reporting surgeon outcomes improve care? | Noncancer | 265 | 60 | 23 | 131 | 49 |

care?' [131 (49%) gave a rating of high importance and 60 (23%) gave a rating of low importance]. Subgroup analysis on those who identified themselves as patients is presented in Table 5. The highest rated question was 'How can diet, probiotics and medicines help in irritable bowel syndrome?' [60 (89% of respondents) gave a rating of high importance and two (3%) gave a rating of low importance]. The lowest rated question for the patient subgroup was the same as the whole group, namely 'Does reporting surgeon outcomes improve care?' [30 (44%) gave a rating of high importance and 16 (23%) gave a rating of low importance].

Discussion

This patient and public consultation exercise explored patients' views on colorectal research topics and prioritized questions for further research. In the patient consultation exercise, participants were found to be supportive of the research questions and highlighted the importance of patient-centred information for recruitment to trials and when selecting outcome measures. Participants, in general, prioritized cancer-related research questions above others, with the top six questions relating to the early diagnosis, treatment and follow up of colorectal cancer. The public consultation exercise was more heterogeneous in prioritizing cancer and noncancer topics. Of note is the high rating of 'How can diet, probiotics and medicines help in irritable bowel syndrome?', which was fourth highest in the public consultation exercise. Professionals did not identify this issue to be an important research topic [15], and it was added to this study at the request of the funder. This finding may represent a potential mismatch between the importance placed on irritable bowel syndrome research by professionals and the public. Further research is needed to explore this issue further and explain the implications for colorectal research.

No other patient or public consultation exercises were identified in the field of colorectal diseases, but comparisons can be made with professionals' prioritization of research topics. Over 918 members of the ACPGBI were surveyed on this issue and the response rate was low, at 239 (26%) [15]. The highest rated cancer question related to the treatment of early rectal cancer and the highest rated noncancer question was on the detection of anastomotic leakage, although effect sizes were not reported. A survey of members of the American Society of Colon and Rectal Surgeons similarly found research on the treatment of rectal cancer to be the most important research question [18]. Somewhat surprisingly, given the evidence that the research community and patients often disagree [21], these topics are exactly those identified as the most important in this public prioritization exercise and offers good triangulation of the present study.

The study is the largest patient and public consultation exercise in colorectal disease undertaken to date, but there are some limitations. The findings from the qualitative study (phase 1) in particular should be interpreted with caution. Data were collected from focus groups by way of field notes that were taken by several different researchers without transcribed audio recordings. This significantly weakens the scientific rigour in a number of ways. It has not been possible to provide a reflective account of all researchers to outline how personal experiences may have resulted in methodological bias. Similarly, note taking was completed in an inconsistent manner, which makes transparent interpretation of the findings difficult. Rich and thick verbatim descriptions [22], commonly used in qualitative research to support findings in sufficient detail to allow extrapolation to other circumstances, were often lacking, which limits the ability of the study to demonstrate clear thought processes during data analysis. The qualitative results of this study have nonetheless been

Table 5 Prioritization of cancer questions by those reporting themselves to be 'patients' in the public consultation: proportion of participants rating each question as 'low' (1 or 2 on the Likert scale) or 'high' (4 or 5 on the Likert scale) in importance.

| Question | Category | Total no. of patients | Low importance | | High importance | |
|--|-----------|--------------------------|-------------------|----|--------------------|----|
| | | | <i>n</i> | % | <i>n</i> | % |
| How can diet, probiotics and medicines help in irritable bowel syndrome? | Noncancer | 73 | 2 | 3 | 60 | 89 |
| What is the best way to treat early cancers in the back passage? | Cancer | 73 | 2 | 3 | 59 | 81 |
| How do we improve screening for bowel cancer? | Noncancer | 71 | 4 | 5 | 58 | 81 |
| How can we improve care for patients with severe infection related to their bowels? | Noncancer | 71 | 5 | 7 | 59 | 81 |
| What is the best way to look after patients with Crohn's disease with fistulas around their bottoms? | Noncancer | 77 | 3 | 4 | 58 | 80 |
| How do we personalize treatment for cancer of the back passage using genetics? | Cancer | 73 | 5 | 7 | 54 | 78 |
| What is the best way to check that cancers of the back passage do not come back? | Cancer | 71 | 4 | 5 | 55 | 77 |
| What is the best way to look after patients with infection from diverticulitis? | Noncancer | 69 | 7 | 9 | 56 | 77 |
| How can we reduce the chances of leakage from a join in the bowel? | Noncancer | 73 | 3 | 4 | 55 | 76 |
| Which polyps predict risk of developing bowel cancer? | Cancer | 67 | 6 | 8 | 56 | 75 |
| What is the best way to close the 'hole' when the anus is removed? | Noncancer | 69 | 5 | 7 | 53 | 72 |
| How do we best treat polyp cancers removed at colonoscopy? | Cancer | 73 | 6 | 8 | 52 | 71 |
| Why do some patients develop spread from bowel cancer? | Cancer | 73 | 4 | 5 | 55 | 71 |
| What is the impact of treatment for bowel and anal cancers on quality of life? | Cancer | 73 | 5 | 7 | 53 | 71 |
| How should we treat patients with cancer in the back passage if they have a really good response to chemoradiotherapy? | Cancer | 75 | 10 | 13 | 47 | 64 |
| When should we operate to remove bowel cancer that has spread to the liver or lungs? | Cancer | 75 | 11 | 15 | 44 | 62 |
| If bowel cancer has spread but responds to chemotherapy, is it worth operating on the primary bowel tumour? | Cancer | 73 | 6 | 8 | 43 | 61 |
| Is chemotherapy better before or after surgery for more advanced bowel cancers? | Cancer | 71 | 12 | 16 | 44 | 60 |
| What are the best ways to prevent and fix hernias beside stomas? | Noncancer | 71 | 8 | 11 | 42 | 57 |
| How do we stop the bowel going on 'strike' after surgery? | Noncancer | 71 | 16 | 23 | 39 | 56 |
| When is it best to use surgery to remove Crohn's disease affecting the bowel? | Noncancer | 73 | 9 | 12 | 38 | 54 |
| Is a more radical approach to surgery for advanced cancers in the back passage beneficial? | Cancer | 69 | 10 | 14 | 38 | 54 |
| When should a join in the bowel have a temporary stoma made above the join? | Noncancer | 69 | 9 | 14 | 37 | 53 |

Table 5 (Continued).

| Question | Category | Total no. of patients | Low importance | | High importance | |
|--|-----------|--------------------------|-------------------|----|--------------------|----|
| | | | <i>n</i> | % | <i>n</i> | % |
| Is there benefit from preoperative radiotherapy in back passage cancers which could be removed with surgery? | Cancer | 73 | 10 | 14 | 37 | 53 |
| Can problems with defaecation be improved by surgery? | Noncancer | 71 | 14 | 21 | 36 | 52 |
| Does reporting surgeon outcomes improve care? | Noncancer | 69 | 16 | 23 | 30 | 44 |

included because it was felt that they were useful supporting data despite these limitations. The findings could be explored more rigorously in future research. The principal weakness of the public consultation exercise is potential selection bias. Participants were recruited from public advertisements and there were no exclusion criteria. It is likely that attendees share certain characteristics that could affect their responses in a way not representative of the UK population as a whole. This may, for example, include the patient's clinical condition, education, level of deprivation or ethnicity. Furthermore, it should be noted that another speaker was discussing treatment options for irritable bowel syndrome at the same public event – it may be the reason why this question scored highly. The public consultation meeting involved the prioritization of many topics in a short period of time. It is therefore important to consider the potential that participants were overwhelmed by information. For example, participants may become fatigued and stop providing scores for questions; however, this did not seem to be the case as the numbers of participants providing scores were stable (257–271; Table 4). Likewise, if participants were overloaded and unable to differentiate between different questions, then the responses may be homogeneous. These data, however, showed a good spread of responses.

The aim of this study was to define a patient-centred research agenda. Now, efforts need to be focussed on designing and conducting high-quality research in these areas. The ACPGBI has begun this process by holding a series of 'Delphi Games', in which multidisciplinary groups of individuals meet to discuss each question and begin to form a research programme. As a direct result, several major studies have been funded in the areas of parastomal hernia (CIPHER) [23], perianal Crohn's disease (ENiGMA) and organ-preserving surgery for rectal cancer (STAR-TREC). In accordance with the findings of this study, patients have been included in all these working groups to help define the subject of

research and the design of the study. Engagement also needs to come from funding bodies. The BDRF has committed research funding to these research questions for a period of 18 months, and other organizations are called upon to recognize the importance of these issues to the colorectal patient community. Further research is also needed to identify further patient-centred areas of research that were not included in this study.

In conclusion, the present study has prioritized a colorectal research agenda in collaboration with patients and the public, and has demonstrated patients' ongoing support for this programme. Further research is required to translate this agenda into real improvement in patient care. 'The great thing about the Delphi ORACLE is that it appeases some of the antagonism between patients and doctors, bringing together the knowledge from objective experts, the clinicians, with the knowledge of the subjective experts, the patients'.

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Appendix I

On behalf of Bowel Research Patient Consultation Exercise (ORACLE) Collaborators: Robert Arnott, Steven Ashdown-Phillips, Simon P. Bach, Nick Bason, Christopher Challand, Anne Demick, Nicola Fearnhead, Richard Gardner, Greg Llewellyn, Robert Lopes de Azevedo Gilbert, Deena Harji, Nick Heywood, Dewi Morgan, Dion Morton, Angus G. K. McNair, John Northover, Jenny Pipe, Joshua Scales, Asha Senapati, Doug Speake, Jim Tiernan, Azmina Verjee, Dale Vimalachandran, Catherine Walter, James Wheeler.